



Appln No.: 09/828,624
Amendment Dated: November 6, 2003
Reply to Office Action of June 13, 2003

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-14 (cancelled)

15. (original) An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00034004.

16. (original) An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00034005.

17. (cancelled)

18. (currently amended) A method for testing for the existence of a menopausal condition in a human female individual, comprising the steps of:

(a) obtaining a gonadotropin-containing sample from the human female individual, wherein the gonadotropin present in the sample exists in a plurality of different forms, and wherein the form or forms in which the gonadotropin exists is different depending on whether or not a menopausal condition exists in the human female individual;

(b) performing contemporaneous first and second assays on the sample obtained in step (a), said first assay producing an indication of the gonadotropin that is independent of the whether the individual is pre- or post-menopausal, and said second assay producing an indication of the gonadotropin that differs depending on whether the human female individual is pre-menopausal or post-menopausal, and

(c) comparing the results of the first and second assays, wherein a difference or similarity between the results of the two assays is indicative of whether the human female individual is pre-menopausal or post-menopausal.

-----19. (previously presented)----- The method of claim 18, wherein the gonadotropin is -----
follicle stimulating hormone (FSH).

20. (previously presented) The method of claim 19, wherein the first and second assays are sandwich-format assays.

21. (previously presented) The method of claim 20, wherein the first assay makes use of a first antibody pair directed against the alpha and beta peptide chains of FSH, and the second assay makes use of a second antibody pair directed against the alpha and beta peptide chains of

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FSH, and wherein both members of the first antibody pair are different from the members of the second antibody pair.

22. (previously presented) The method of claim 21, wherein the first antibody pair detects total FSH.

23. (previously presented) The method of claim 21, wherein the first and second assays each provide a quantitative result, and the ratio of the two results is determined as an indication of menopausal status.

24. (currently amended) The method of claim 21, further comprising the step of repeating the two contemporaneous assays after an interval of at least one week to determine is if the menopausal status of the human female individual is changing.

25. (previously presented) The method of claim 24, wherein the human female individual is one undergoing a course of hormone replacement therapy.

26. (previously presented) The method of claim 18, wherein the first and second assays are sandwich-format assays.

27. (previously presented) The method of claim 26, wherein the first assay makes use of a first antibody pair directed against the alpha and beta peptide chains of the gonadotropin, and the second assay makes use of a second antibody pair directed against the alpha and beta peptide chains of the gonadotropin, and wherein both members of the first antibody pair are different from the members of the second antibody pair.

28. (previously presented) The method of claim 27, wherein the first and second assays each provide a quantitative result, and the ratio of the two results is determined as an indication of menopausal status.

29. (previously presented) The method of claim 28, further comprising the step of repeating the two contemporaneous assay after an interval of at least one week to determine is menopausal status of the human female individual is changing.

30. (previously presented) The method of claim 29, wherein the human female individual is one undergoing a course of hormone replacement therapy.

31. (currently amended) An assay device for determination of menopausal status of a human female individual by testing of a sample of body fluid, comprising:

(a) a first gonadotropin-responsive signal producing means that, relative to a

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reference standard, produces a signal indicative of the gonadotropin present in the sample that is independent of the whether the individual is pre- or post-menopausal condition of the human female individual;

(b) a second gonadotropin-responsive signal producing means that, relative to a reference standard, produces a signal indicative of the gonadotropin present in the sample that is different depending on the whether the individual is pre- or post-menopausal condition of the human female individual; and

(c) means for combining the signals ~~for~~ produced by the first and second gonadotropin-responsive signal producing means to provide an indication of the menopausal status of the human female individual.

32. (previously presented) The assay device of claim 31, wherein the first and second gonadotropin-responsive signal producing means produce signals indicative of follicle stimulating hormone (FSH).

33. (currently amended) The assay device of claim 32, wherein the first and second gonadotropin-responsive signal producing means each produce a signal as a result of binding in a detection zone of a labeled specific binding reagent with a particulate direct label.

34. (currently amended) The assay device of claim 32 33, wherein said labeled specific binding reagent is an antibody directed against the alpha or beta peptide chains of FSH.

35. (previously presented) The assay device of claim 31, wherein the first and second gonadotropin-responsive signal producing means each produce a signal as a result of binding in a detection zone of a labeled specific binding reagent with a particulate direct label.